

### **REMARKS/ARGUMENTS**

Applicants respectfully request reconsideration of this application in light of the claim amendments and arguments presented herein.

By the amendments, Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

#### **In the Claims**

Claims 27-29, 31, 32, 35, 37-39 and 44 are amended herein. No new matter has been introduced as a result of the claim amendments.

Claim 27 has been amended to recite that the first assay comprises a first test strip that measures glycated albumin and the second assay comprises a second test strip that measures total albumin. Claim 27 has further been amended to include, as part of the claimed system, a single application pad containing a sample well and to indicate that the first and second test strips have disposed therein include microparticles which specifically bind to components of the sample. Support for the amendments to claim 27 can be found in claims 31, 44, paragraphs [0037] and [0040] of the specification and Figure 1-3 and 5-7.

Claims 28 and 29 have been amended to recite that the assays measure either glycated albumin or total albumin by the claimed steps and that the antibodies comprise antibody-coated microparticles.

Claim 31 has been amended to remove reference to the first test strip and the second test strip, subject matter that has been incorporated into claim 27, and now recites that the means for calculating percent glycated albumin comprises the claimed measurement device.

Claims 32 and 35 have been amended to replace the term "comprised" with language indicating that the microparticles are disposed in the test strips. The test

strips are not made of microparticles but rather include them as one of several components. Support for this amendment can be found in claim 44. These claims were also amended to correct dependency.

Claim 37 has been amended to replace the phrase "may be" with "are".

Claim 38 has been amended to correct dependency and to accurately recite the different strip arrangements as a Markush group.

Claim 39 has been amended to correct dependency.

Claim 44 has been amended to clarify the migration of the blood plasma-bound antibody-coated microparticles in the fifth and sixth steps and to indicate that the sample well is a single sample well. Support for the amendments to claim 44 can be found in Figure 1-3 and 5-7. Claim 44 has also been amended to replace the term "visible" with the phrase "colored or fluorescent". Support for this amendment can be found in claim 27.

### **35 U.S.C. §112 Rejections**

Claims 27-44 have been rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 27-29 were rejected as vague and indefinite because the Office alleges that the preamble is directed to a system and the body of the claim is directed to steps of an assay. Applicants have amended claim 27 to better recite the components of the system, specifically a single application pad containing a sample well, a first assay comprising a first test strip that measures glycated albumin, a second assay comprising a second test strip that measures total albumin, and means for calculating percent glycated albumin. The components of the claimed system are not method steps but rather components of the test system.

Claims 32 and 35 were rejected as vague because the Office alleges they are not clear as to how the microparticles are related to the test strip. Claims 32 and 35

have been amended to state that the test strips have microparticles disposed therein. The test strips are not made of microparticles but rather include them as one of several components.

Claim 44 was rejected as vague because it was not clear as to which complexes are being referred to in lines 12-15. Claim 44 has been amended to recite that the antibody-coated microparticles in each of the first test strip and the second test strip independently migrate.

Therefore, in light of the claim amendments, Applicants respectfully assert that the pending claims are not indefinite under 35 U.S.C. §112, second paragraph and request the withdrawal of the rejection on this basis.

#### **Double Patenting**

Claims 27-30 have been provisionally rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims 1, 2, 8, 9, 11, 14 and 15 of co-pending application number 11/140,306 (hereinafter "the '306 application") and claims 1, 4, 12 and 13 of co-pending application number 11/474,561 (hereinafter "the '561 application").

The instant application is the earlier filed application in both instances. Furthermore, the claim scope of any patents issuing from these co-pending applications is not possible to determine at this time.

However, Applicants respectfully assert that the instant claims are patentably distinct from the claims currently pending in the '306 and '561 applications because the instant claims are drawn to a system for detecting glycated albumin in a test sample comprising a first test strip and a second test strip. The claims in the co-pending applications are drawn to systems comprising a single test strip.

Therefore, the claimed systems are not the "same invention" as the systems claimed in the co-pending '306 and '561 applications. There is no system that would infringe the present claims that would also infringe a claim of these other applications.

Thus, there is no way the Applicant could sue these later applications to extend the exclusivity of any embodiment protected by the claims.

Therefore, Applicants respectfully request the withdrawal of the non-statutory obviousness type double patenting rejections.

### **35 U.S.C. §102 Rejections**

Claims 27-31, 33, 38, 39 and 44 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Yamamoto et al. (EP 0 769 697 A1). Applicants respectfully disagree.

A claim is anticipated under 35 U.S.C. §102 only if each and every element as set forth in a claim is found, either expressly or inherently described, in a single prior art reference (MPEP §2131; *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d, 628, 631, 2 USPQ2d 1051 (Fed. Cir. 1987)). A claimed invention is anticipated only when it is "known to the art in the detail of the claim." *Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). In other words, not only must the limitations of the claim be shown in a single prior art reference, the limitations must be "arranged as in the claim." *Id.*

Yamamoto et al. discloses a method and a dry test apparatus for simultaneously determining total albumin and glycated albumin. However, Applicants respectfully note that while Yamamoto calls the test apparatus "dry" it requires the addition of a developer defined in column 8, line 56 through column 9, line 6 as a buffer solution containing trace amounts of protein, a salt, a chelate compound, a surfactant and the like. A 0.1M phosphate buffer solution containing 0.1% bovine serum albumin, 0.9% sodium chloride, 0.01% EDTA, and 0.01% Triton X-100 can be mentioned as a typical example of the developer." The presently claimed system does not require the addition of an exogenous developer.

Amended claims 1 and 44 require only a single application pad containing a sample well. All the embodiments of Yamamoto having two developing layers require two sample application sites, E and E', as depicted in Figures 1A and 4A. The instant

claims require only one sample application site which allows sample to pass into the two assay test strips.

Furthermore, Yamamoto discloses the use of dyes as indicators while the instant claims require microparticles. Yamamoto does not disclose microparticles as indicators.

Therefore, Yamamoto does not disclose all the elements of claims 27-31, 33, 38, 39 and 44 and as such, the Applicants request the Office withdrawal of the rejection under 35 U.S.C. §102(b) on this basis.

### **35 U.S.C. §103 Rejections**

I. Claims 32 and 34-37 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yamamoto et al. in view of Chudzick et al. or Kang et al. Applicants respectfully disagree.

To maintain a proper rejection under 35 U.S.C. §103, the Office must meet four conditions to establish a *prima facie* case of obviousness. First, the Office must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the Office must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in the applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the Office must show a suggestion, teaching, or motivation to combine the prior art references ("the TSM test"). *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). Following *KSR Int'l Co. v. Teleflex, Inc.*, this fourth prong of the *prima facie* obviousness analysis must not be applied in a rigid or formulaic way such that it becomes inconsistent with the more flexible approach of *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966); 127 S. Ct. 1727 (2007). It must still be applied, however, as the TSM test captures the important insight that "a patent composed of several elements is not proved obvious merely by

demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 1741 (citing *United States v. Adams*, 383 U.S. 39, 50-52 (1966)).

As discussed *supra*, Yamamoto et al. does not teach or suggest all the elements of the pending claims. Kang was cited for its teaching of the use of dyes or particles, such as colloidal metal particles or sol particles that are colored or colored polymeric particles to label immunoreagents on test strips. Chudzik was cited for its teaching of the use of metal sols, dye sols or particulate latex as labels for tagging immunoreagents used on test strips.

The teachings of Kang or Chudzik do not remedy the deficiencies of Yamamoto. The combination of Yamamoto and Kang or Chudzik do not teach or suggest all the elements of the pending claims, specifically a system for detecting glycosylated albumin in a sample and determining the percent glycosylated albumin comprising a single application pad containing a sample well, a first assay comprising a first test strip that measures glycosylated albumin in said sample, a second assay comprising a second test strip that measures total albumin in the same sample as said first assay; and means for calculating percent glycosylated albumin, wherein said first assay and said second assay include microparticles which specifically being components of said sample.

Furthermore, persons of ordinary skill in the art understand that indicator particles cannot be simply substituted for indicator dyes due to the significant physical and chemical differences between the two materials. For example, it is well known to persons of ordinary skill that the flow of the indicator bound analyte through an immunochromatographic device is dependent on the size of the indicator-bound analyte complex and the porosity of the membrane strip. The size of the soluble dye complex taught by Yamamoto is several orders of magnitude smaller than the particle complexes taught by Kang or Chudzik. Therefore, even if the combination of Yamamoto and Kang or Chudzik disclosed all the elements of the claimed invention, which Applicants respectfully assert they do not, there is no expectation of success in achieving the claimed invention by combining the particles of Kang or Chudzik with the assay of Yamamoto.

Based on the foregoing, Applicant respectfully requests that the Office reconsider and withdraw the pending rejection of claims 32 and 34-37 under 35 USC §103(a).

II. Claims 40-43 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yamamoto et al. in view of Galen et al. Applicants respectfully disagree.

As discussed *supra*, Yamamoto et al. does not teach or suggest all the elements of the pending claims. Galen was cited for teaching a reflectance spectrometer.

The teachings of Galen do not remedy the deficiencies of Yamamoto. The combination of Yamamoto and Galen do to teach or suggest all the elements of the pending claims, specifically a system for detecting glycated albumin in a sample and determining the percent glycated albumin comprising a single application pad containing a sample well, a first assay comprising a first test strip that measures glycated albumin in said sample, a second assay comprising a second test strip that measures total albumin in the same sample as said first assay; and means for calculating percent glycated albumin, wherein said first assay and said second assay include microparticles which specifically being components of said sample and wherein the means for calculating percent glycated albumin is a reflectance spectrometer or a fluorometer. Based on the foregoing, Applicant respectfully requests that the Office reconsider and withdraw the pending rejection of claims 40-43 under 35 USC §103(a).

**Conclusion**

Applicants respectfully assert that, in light of the arguments and claim amendments presented herein, the claims are in condition for allowance and Applicant requests that a timely Notice of Allowance be issued in this case.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

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